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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,854	01/15/2004	Russell John Fischer	Fischer01	4608

7590 12/08/2006
Russell Fischer
17 Woodland Rd.
Bernardsville, NJ 07924

EXAMINER

MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,854

Applicant(s)

FISCHER, RUSSELL JOHN

Examiner

Jon-Eric C. Morales

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/12/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 13 is objected to because of the following informalities: Claim 13 recites the limitation "said magnitude of atrial rate modulation and said magnitude of ventricular rate modulation" in line 11 and 12 on page 19. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.
2. Claims 6 and 10 are objected to because of the following informalities: Claim 6 and 10 cite the limitation "the inverse of a time interval". There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 8, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Olive (US Patent No. 5107850). Olive discloses an atrial (first chamber) sensing electrode and a ventricular (second chamber) sensing electrode, which are implanted appropriately in the respective chamber and used to detect electrical activity rates (depolarizations) of the atria and ventricles (column 2 lines 25-32). The atrial and ventricular rates and the standard deviation of both are continuously averaged over a predetermined time sample period (column 3 lines 38-42). Atrial rate modulation is determined by checking if the atrial rate is regular by comparing the standard deviation

of the atrial rate with one-tenth of the value of the atrial rate (column 4 lines 58-64, Fig. 2E). Ventricular rate modulation is determined by checking if the ventricular rate is regular by comparing the standard deviation of the ventricular rate with one-tenth of the value of the ventricular rate (column 5 lines 4-10, Fig. 2E). The ventricular rate, if found greater than a threshold value, is compared (analyzed) to the atrial rate, here it can determine if ventricular tachycardia or fibrillation is occurring (column 3 lines 52-61).

Regarding claim 11, the atrial rate and ventricular rates are averaged (measure of rate modulation) over a period of time (column 3 lines 38-41). Then the measure of similarity of the atrial and ventricular rates is determined by the comparison of the absolute values of the difference in rate to the mean separation (column 3 lines 66-67, column 4 line 1).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olive (US Patent No. 5107850) as applied to claim 2 above, and further in view of Schroeppel et al. (US Patent No 5749900). Olive discloses the invention substantially as claimed, however does not disclose calculating a time interval between successive atrial and ventricular depolarizations to determine a magnitude value of the atrial and ventricular depolarization period and forming a time series with the magnitude values. Schroeppel et al. discloses that the time between successive atrial or ventricular depolarizations are measured within the atrium or ventricle, respectively. These values are the A—A interval or V—V interval (magnitude) (column 6 lines 61-67, column 7 lines 1-3). A—A or V—V intervals are continuously recorded for successive epochs (time series) lasting for several minutes (column 7 lines 10-16). Schroeppel et al. shows that this step of measuring the atrial and ventricular intervals can assist in defining normal and abnormal heart rate variability (dysfunction). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Olive by adding time interval and series detection of the atrial or ventricular depolarizations, as taught by Schroeppel et al., in order to facilitate forming a atrial and ventricular rate signal that can help determine cardiac dysfunction.

6. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olive (US Patent No. 5107850) as applied to claim 2 above, and further in view of Duffin (US Patent No. 5193550). Olive discloses the invention substantially as claimed, however does not disclose calculating an inverse time interval between successive atrial and ventricular depolarizations to determine a magnitude value of the atrial and

ventricular depolarization period and forming a time series with the magnitude values. Duffin measures the atrial and ventricular rates by measuring intervals between successive P-waves and R-waves (column 9 lines 62-65). The atrial and ventricular intervals are then transformed into a rate of recurrence in beats/min (formed into time series) (column 11 lines 14-21). Duffin shows that measuring atrial and ventricular rates between successive P-waves and R-waves assists in discriminating between normal and pathologic tachycardia (cardiac dysfunction). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Olive by adding inverse time interval and time series detection of the atrial and ventricular depolarizations, as taught by Duffin, in order to discriminate between normal and pathologic tachycardia (cardiac dysfunction).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olive (US Patent No. 5107850) as applied to claim 2 above, and further in view of Armstrong et al. (US Patent No. 5713366). Olive discloses the invention substantially as claimed, however does not disclose a displaying means for the measures of atrial and ventricular rate modulation to a user for comparison. Armstrong et al. discloses that both atrial and ventricular rate or intervals are plotted over time on an external graphic display. The display helps physician give better diagnosis by able to see each signal and compare to one another. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Olive by including an external graphic display as taught by Armstrong et al., in order to facilitate visual comparison of the atrial rate modulation and ventricular rate modulation.

Conclusion

The following patent and patent application publications are cited and further show the state of the art with respect to predicting cardiac dysfunction using measurement and comparison of atrial and ventricular rate signal from the heart in general:

Akhtar – 5411530

Lu – 6697673

Kieval et al. – 5626623

Bornzin et al. – 5810739

Begemann – 6636762

Mann et al. – 5788717

Mo – 6611714

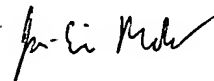
Randall – 4245647

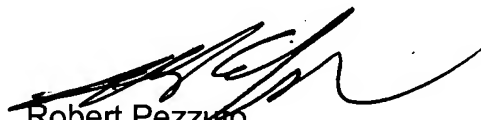
McClure - 5632936

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is (571) 272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jon-Eric Morales
Patent Examiner
Art Unit 3766


Robert Pezzato
Supervisory Patent Examiner
Art Unit 3766

JEM